UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **All Wave II TVT Cases** **All Wave II Gynemesh Cases** ***Bonnie Maxwell v. Ethicon, Inc., et al*** **Case No. 2:12-cv-02138** ***Karen Swanson v. Ethicon, Inc., et al*** **Case No. 2:12-cv-01709**	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE GENERAL OPINION TESTIMONY OF ROBERT M. ROGERS, M.D.

Introduction and Summary

Plaintiffs seek to exclude Dr. Rogers's opinions (1) about Ethicon's cadaver studies related to TVT and (2) about the professionalism and compliance with industry and government standards he observed at Ethicon. For the reasons set forth below, Ethicon believes Dr. Rogers should be allowed to testify on these matters consistent with this Response.

ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Rogers Has Extensive Experience Related to Cadaver Studies and Should Be Permitted to Testify Fully Regarding That Experience.

Plaintiffs argue that Dr. Rogers should not be allowed to offer any opinions about or related to cadaver studies conducted by Ethicon concerning TVT, as Dr. Rogers admitted that he had no knowledge of those studies. Ethicon does not dispute that Dr. Rogers did not participate in the earliest cadaver studies on TVT. Dr. Rogers, however, has unique and vast experience performing cadaver studies with Ethicon and publishing on female anatomy, including those for TVT-O and TVT-Secur. Plaintiffs seek a universal limitation on Dr. Rogers's testimony regarding cadaver studies, even though Dr. Rogers has significant expertise in cadaver studies that involve the same mesh and general anatomical location as the TVT device. While the devices utilize different approaches or routes, the TVT-Secur may use the same approach ("retropubic") as the TVT device at issue in these cases.

Dr. Rogers's General Report describes his extensive cadaveric experience, both independently and on behalf of Ethicon. Ex. A, TVT General Report at pp. 1-3 and 5-6. For example, Dr. Rogers stated

> From the late 1990s to 2007, I was asked by the research and clinical scientists at Ethicon to consult with them on the design and performance of the Prolift, TVT-O, TVT-Secur products, as well as one or two other developing products. I was asked to perform cadaver dissections to be sure that proper surgical dissection techniques would allow proper and safe placement of the various polypropylene mesh products. I was also involved in developing teaching methods for instruction of other pelvic and vaginal surgeons on why and how to use these mesh products, the pelvic anatomy, the properties of the mesh, and the safe and effective use of the products.

Id. at 5. Dr. Rogers simply cannot separate his vast knowledge of the cadaver studies from his general opinions simply because he was not involved in the earliest TVT cadaver studies. Indeed, when the FDA cleared TVT-O and TVT-Secur as substantially equivalent to TVT, it necessarily found that those devices were "as safe and effective" as TVT because TVT was a predicate device for both. *See* 21 U.S.C. 360(c)(i). Dr. Rogers's opinion regarding the general efficacy of

TVT is clearly based upon his experience with cadaver studies, both generally and on similar products the FDA has declared to be substantially equivalent to TVT, and cannot be parsed in the way Plaintiffs seek.

Plaintiffs also seek to exclude Dr. Rogers's opinions regarding the clinical efficacy of the TVT device, claiming that such opinions are outside the scope of his expert opinion. However, Dr. Rogers's TVT General Report states that he has performed "over 200 midurethral slings on these patients, most of them involving the suprapubic midurethral TVT, TVT-O, and TVT-Secur products." *Id.* at 3. Dr. Rogers's report also provides a review of the literature and opinions on the efficacy of various TVT devices. *Id.* at 12-19. Certainly, a surgeon with Dr. Rogers's experience is allowed to examine the literature and offer such an opinion. *See Wilkerson v. Boston Sci. Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *24 (S.D. W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit.").

Plaintiffs here seek more than a mere exclusion of Dr. Rogers's expert opinions on specific cadaver studies; they seek instead to exclude all his opinions related to cadaver studies, even where those opinions provide reliable, trustworthy evidence that is relevant and helpful. Dr. Rogers's opinions related to his experience and work on cadaver studies should be permitted.

II. Dr. Rogers Should Be Permitted to Testify Regarding the Thoroughness of His Work with Ethicon.

Plaintiffs seek to exclude Dr. Rogers's testimony related to Ethicon's "good acts." Dr. Rogers's report contains no opinion that Ethicon is a "good company." Instead, Plaintiffs characterize as impermissible character evidence Dr. Rogers's testimony that his interactions

with Ethicon "research scientists, biomedical engineers and clinicians were consistently respectful, appreciated, and honest" and that product development was "in accordance to the Ethicon standards, the industry standards, and of course, the FDA and federal government standards." Ex. A, TVT General Report at p. 5; Ex. B, Gynemesh General Report at p. 7. Plaintiffs also cite Dr. Rogers's opinions that Ethicon's professional education development "was sincere and thorough" and that product development at Ethicon had "the patients' best interests always at the top of each agenda," and was "in earnest."[1] Ex. A, TVT General Report at p. 6; Ex. B., Gynemesh General Report at pp. 8-9.

This is clearly *not* inadmissible character evidence and is, instead, an opinion based on Dr. Rogers's specialized knowledge regarding product development, clinical studies, and professional education, and his experiences working with Ethicon in these areas. Such testimony is admissible. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) ("Experts of all kinds tie observations to conclusions through the use of what Judge Learned Hand called 'general truths derived from . . . specialized experience.'").

Dr. Rogers should be permitted to testify regarding the thoroughness of the clinical studies, product development, and professional education he was involved with. Dr. Rogers has specialized knowledge and experience in clinical studies, product development, and professional education. His specific evaluation of his experience in these areas with respect to Ethicon is relevant, reliable, and admissible. Ethicon requests that, should the Court limit Dr. Rogers's testimony in this regard, Dr. Rogers should be able to testify to his experience regarding the

[1] Ethicon notes that Plaintiffs' interpretation of Dr. Rogers's use of the phrase "in earnest" is taken out of context and is inaccurate. The context of the statement appears to use "in earnest" to mean "occurring to a greater extent or more intensely than before" rather than "sincere and serious." *See Oxford Dictionaries*, *available at* http://www.oxforddictionaries.com.

design and development of similar products, feedback on product development, cadaver labs, and professional education content.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' Motion and allow Dr. Rogers's testimony consistent with this Response.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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